UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, DC 20460



OFFICE OF PREVENTION, PESTICIDES AND TOXIC SUBSTANCES Antimicrobials Division

February 26, 2002

SUBJECT: PRODUCT CHEMISTRY REVIEW OF: Dishwasher Magic

DP Barcode: D280130

Reg. No. Or File Symbol: 74286-R

Manufacturing-use [] OR.

End-use Product [X]

TO:

Adam Heyward PM 34 / Drucilla Copeland, Team Reviewer

Regulatory Management Branch II Antimicrobials Division (7510C)

FROM:

Robert Turpin, Chemist

Product Science Branch, CT Team

Antimicrobials Division (7510C)

THRU:

Karen P. Hicks, CT Team Leader

Product Science Branch

Antimicrobials Division (7510C)

THRU:

Michele E. Wingfield, Chief

Product Science Branch

Antimicrobials Division (7510C)

Product Formulation

Active Ingredient(s)

% by wt.

Citric acid

... 25.00

BACKGROUND: The applicant has submitted an application for registration of its product, Dishwasher Magic. In support of the application is submitted a revised Confidential Statement of Formula, dated 8/14/01, and a certificate of analysis for citric acid, the active ingredient, from the supplier for the subject product. Received from the supplier of the fragrance used in the subject product is a list of components, said list containing the CAS number and percent of composition of each component contained therein. The Product Science Branch has performed the primary review.

FINDINGS:

The active ingredient, citric acid, is provided by an unregistered source.

RECOMMENDATIONS:

The applicant is required to submit to the agency a certificate of analysis. The letter enclosed in MRID #455702-01, Volume 1, does not satisfy the requirements of a Certificate of Analysis. The certificate must indicate the enforcement analytical method used by the supplier to determine purity and an actual result of the analysis of the product received by the applicant.

PRODUCT CHEMISTRY REVIEW CONFIDENTIAL STATEMENT OF FORMULA

4a.	Type of formulation and source registration
	Non-integrated formulation system Are all TGAIs used registered? Yes [] No [X]
	Integrated formulation system []
	if "ME-TOO", specify EPA Reg. # of existing product:
4b.	Clearance of inerts for non-food or food use: Cleared for food use under 40 CFR §180.1001: Yes [] No [X] NA[]
4c.	Physical state of product: Liquid
4d.	The chemical IDs and analytical information (including that for the TGAIs), density, pH, and flammability are consistent with that given in 830, Part B Yes [] No [X]
4h.	NCs and CLs are acceptable: Yes [X] No [] Not acceptable []
4i.	Active ingredient (s) NC LCL UCL Citric acid 25.00% 24.25% 25.75%
4j	j. For products produced by an integrated formulation system: All impurities of toxicological significance have a UCL? Yes [] No [] Not applicable [X]
•	All impurities of ≥ 0.1% in the product have been identified? Yes [] No [] Not applicable [X]

5. PRODUCT LABI	EL
-----------------	----

5a.	The active ingredients statement (chemical IDs and with the CONFIDENTIAL STATEMENT OF FO			No f
	WILLIAM STATEMENT OF FO	MWOLA:	I es [A]	No [
5b.	The formulation contains one of the following:			
	• 10% or more of a petroleum distillate:	Yes []	No [X]	
	 1.0% or more of methyl alcohol: 	Yes []	No [X]	
	 Sodium nitrite at any level: 	Yes []	No [X]	
	 a toxic List 1 inert at any level: 	Yes []	No [X]	
	arsenic in any form:	Yes []	No [X]	
	footnote indicating this? Yes [] No [] No	t applicable	[X]	
	footnote indicating this? Yes [] No [] No	t applicable	[X]	
5d.	The appropriate warning statement regarding flammar characteristics of the product are listed on the label?	ability or exp	olosive	
	Yes []No [] Not applicable [2	(]		
5e.	The storage and disposal instructions for the pesticid	e and contain	ner are	
	in compliance with PR Notice 84-1 for household us			
	83-3 for all other uses? Yes [] No [X			
5f.	Does the product require an expiration date at which	time the NC	falls	

below the LCL (based on the one year storage stability data or other information)?

No [X]

Yes []

PRODUCT CHEMISTRY (830 Series, Part B)

Guideline	Acceptance of Information	MRID No.
830.1550 ¹ Product Identity	A	454814-01
830.1600 Description of Materials	A	454814-01
830.1620 Production Method ²	A	454814-01
830.1650 Formulation process ³	NR	
830.1670 Formation of impurities ⁴	NR	
830.1700 Preliminary Analysis ⁵	A	Reregistration document
830.1750 Certified Limits ⁶	A	CSF
830.1800 Analytical Method ⁷	Acid-base titration	454814-01

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

4.

¹See Confidential Appendix A for additional information

²For MP/EP products produced by an integrated formulation system.

³For products from a TGAI or MP.

⁴May be waived unless actual/possible impurities are of toxicological concern.

⁵Five batch analysis required for products produced by an integrated formulation system.

⁶If different from standard Cls recommended in 40 CFR 158.175, this should be discussed in Confidential Appendix A.

⁷Abbreviate method used as follows: gas chromatography (GC), infrared (IR), ultraviolet absorption (UV), nuclear magnetic resonance (NMR), etc.

6b. <u>Physical/Chemical</u> <u>Properties</u> *	Acceptance of data	Value or qualitative description	MRID No.
830.6302 Color	A	Clear and colorless	454814-02
830.6303 Physical state	A	Liquid	454814-02
830.6303 Odor	NR		
830.7200 Melting point	NA		
830.7220 Density/Relative density/bulk density	A	1.109 g/ml	454814-02
830.7000 pH ¹	A	2.2 +/- 0.01 @ 1% aqueous	454814-02
830.6314 Oxidation/Reduction	A	Contains no oxidizer or reducing agent	454814-02
830.6315 Flammability	A	Contains no flammable components	454814-01
830.6317 Storage stability	A	Pending	454814-02
830.7100 Viscosity	A	2.117 cP	454814-02
830.6319 Miscibility ²	NA		
830.6320 Corrosion Character.	A	Pending	454814-02
830.6321 Dielectric breakdown	NA		

Explanation: A=acceptable; N=not acceptable; NA=technically not applicable; G=data gap; U=requires upgrading; W=waived; E=EPA estimate.

^{*} Provide brief description, e.g., color--yellow or property value, e.g., density 1.25 g/cc; Unless otherwise indicated, the property should be at 25 0 C.

- ¹ If product is dispersible with water
- ² If product is an emulsifiable liquid